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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,098	09/20/2001	Yukio Toyoda	46342/56000	9857

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EXAMINER	
LEFFERS JR, GERALD G	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/869,098	TOYODA ET AL.	
	Examiner	Art Unit	
	Gerald G Leffers Jr., PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 May 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/14/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of an amendment, filed 5/14/2004, in which claims were amended (claims 1-8 and 11) and in which claims were cancelled (claims 9-10 and 12-14). Claims 1-8 and 11 are pending in the instant application and are under consideration.

Any rejection of record not addressed herein is withdrawn. This action is not final as there are new grounds of rejection made herein that were not necessitated by applicants' amendment of the claims.

Drawings

The replacement drawings were received on 5/14/2004. These drawings are accepted.

Sequence Compliance

Receipt is acknowledged of a replacement paper copy of the sequence listing, corresponding computer readable form (CRF) and appropriate attorney's statements concerning the sequence listing and CRF. The application is now in sequence compliance.

Information Disclosure Statement

Receipt is acknowledged of a pair of information disclosure statements, filed 5/14/2004. The signed and initialed PTO Form 1449's have been mailed along with this action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **The following are new rejections.**

Claim 1 recites the limitation of an isolated DNA or promoter region "containing" a regulator sequence. The term "containing" is not explicitly defined in the instant specification and it is not clear whether the term is meant to be open (e.g. comprising) or closed language (e.g. consisting of), making the metes and bounds of the DNA claimed unclear. It would be remedial to amend the claim to include language that is explicitly open (e.g. comprising) or closed (e.g. consisting of) with regard to the presence of additional elements.

Claim 1 lacks articles (e.g. "a" or "the") prior to several elements of the claim (e.g. "uncoupling protein-2 (UCP-2) promoter region" or "peroxisome proliferator response element (PPRE)"). The lack of such articles prior to different elements of the claim makes it unclear as to how many or which of the particular element are to be present in the claimed nucleic acid. Claims 2, 3, 6 and 11 also lack articles prior to specific elements recited in the claim, making it unclear how many of the specific elements are necessarily present in the claimed invention (e.g. claim 6, UCP-2 promoter region or regions?).

Claim 1 is vague and indefinite in that the metes and bounds of the phrase "wherein the regulator sequence is at least any one of the sequences selected from" are unclear. It is unclear whether the term "is" is necessarily closed language or not. It would be remedial to amend the claim to include language that is explicitly open (e.g. comprising) or closed (e.g. consisting of) with regard to the presence of additional elements.

Claim 1 is further vague and indefinite in that the metes and bounds of the phrase "presented by" with regard to sequences within SEQ ID NO: 1. The term is not explicitly defined in the instant specification and it is unclear whether the term specifies that the particular nucleotide residues recited in the claims are necessarily present in the claimed nucleic acids or that the claimed sequences merely comprise nucleotide residues that "correspond to" or are "represented by" the specific recited residues of SEQ ID NO: 1. it would be remedial to amend the rejected claims to clearly indicate which of the two possibilities is intended by the term "presented by" (e.g. "comprising nucleotides 284 to 296 of SEQ ID NO: 1").

Claim 1 is vague and indefinite in that the metes and bounds of the term "a sequence comprising MyoD" are unclear. It is unclear if MyoD is a protein or is a protein-binding site within the polynucleotide sequence of SEQ ID NO: 1. If the term actually refers to a protein-binding site within the polynucleotide sequence of SEQ ID NO: 1, it would be remedial to amend the claim to something like "a sequence comprising a MyoD-binding sequence".

Claim 8 is vague and indefinite in that there is no clear and positive prior antecedent basis for the phrase "the transformant lacking the UDP-2 promoter contacted to the test compounds.

Claim 11 is vague and indefinite in that the metes and bounds of the phrase "cell differentiation medium" are unclear. The term is not explicitly defined in the specification and it is unclear what components or functional characteristics are encompassed by the phrase. It would be remedial to amend the claim language to clearly indicate what is intended by the cited phrase.

Claim 11 is further vague and indefinite in that the metes and bounds of the phrase "plasmid for measurement of UCP-2 promoter activity" are unclear. The instant specification

does not clearly indicate that is considered to be the minimal elements required for a plasmid to satisfy the limitation of being a "plasmid for measurement of UCP-2 promoter activity". It would be remedial to amend the claim language to clearly indicate the minimal elements required to satisfy the cited phrase.

Claim 11 is vague and indefinite in that it is unclear how a kit can "consist of" only the elements recited in the rejected claim (i.e. two different types of media, a plasmid(s) for measurement of UCP-2 promoter activity, host cell line and test compounds).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection necessitated by applicants' amendment of the claims in the papers filed 5/14/2004.**

The rejected claim is directed to a "kit" comprising the following elements: two different types of media, a plasmid(s) for measurement of UCP-2 promoter activity, host cell line and test compounds. The term "a plasmid(s) for measurement of UCP-2 promoter activity" is not clearly defined in the instant specification and can be interpreted broadly to read on any type of plasmid that may be used, directly or indirectly, to measure UCP-2 promoter activity. Similarly, the term

"cell differentiation medium" is not clearly defined and can be interpreted broadly to encompass any type of media in which any type of cell can undergo any degree of differentiation under any conditions. Further, the claim encompasses literally any type of test compound that might be used in any assay, direct or indirect, that measures UCP-2 promoter activity. Thus, the rejected claims encompass an enormous genus of different combinations of elements, each of which is recited in enormously broad terms.

Given that the instant specification appears to be directed to a very specific set of hUCP-2 promoter sequences (i.e. SEQ ID NO: 1), that only 1 example is provided for what constitutes a "cell differentiation" medium and that the description provided for what constitutes a "test compound" is only generic with regard to classes of different compounds, and given the enormous genus of combinations of elements recited by the rejected claim, the skilled artisan would not have been able to envision a sufficient number of specific embodiments of the claimed invention to described the broadly claimed genus. Therefore, the skilled artisan would reasonably have concluded applicants were not in possession of the claimed invention.

Claim Rejections - 35 USC § 102

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Amaral et al (U.S. Patent No. 5,807,740 issued 9/15/1998) or Amaral et al (U.S. Patent No. 5,849,514 issued

12/15/1998). **This is a new rejection necessitated by applicants' amendment of the claims in the papers filed 5/14/2004.**

The rejected claim is directed to a "kit" comprising the following elements: two different types of media, a plasmid(s) for measurement of UCP-2 promoter activity, host cell line and test compounds. The term "a plasmid(s) for measurement of UCP-2 promoter activity" is not clearly defined in the instant specification and can be interpreted broadly to read on any type of plasmid that may be used, directly or indirectly, to measure UCP-2 promoter activity. Similarly, the term "cell differentiation medium" is not clearly defined and can be interpreted broadly to encompass any type of media in which any type of cell can undergo any degree of differentiation under any conditions. Further, the claim encompasses literally any type of test compound that might be used in any assay, direct or indirect, that measures UCP-2 promoter activity. Thus, the rejected claims encompass an enormous genus of different combinations of elements, each of which is recited in enormously broad terms.

Both patents disclose DNA containing a promoter region which includes a human USP-2 regulator sequence and has a nucleotide sequence that coincides with bases 1762 to 2280 of SEQ ID NO: 1 (e.g. a "part thereof as in claim 4). In particular, cells transformed with UCP-2 promoters operably linked to reporter genes are taught for use in drug screening assays (e.g. Abstract, columns 3-4). The cell media disclosed by the patents (e.g. DMEM/F12/12% FBS) can reasonably be interpreted to be both a cell growth media as well as a "cell differentiation" media given the lack of a clear definition for what constitutes a "cell growth medium". Therefore, both patents anticipate the claimed kit.

Claims 1-8 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Surwit et al (WO 98/31396; see the entire PCT application). **This is a new rejection.**

The Surwit et al application teaches the identification and cloning of nucleic acid sequences encoding human uncoupling protein 2 (hUCP-2), 5' sequences controlling the expression of hUCP-2 as well as methods of using the regulator sequences to identify modulators of hUCP-2 expression. For example, the application teaches the identification of a human BAC clone comprising approximately 20 kb of human sequence which the practitioners believe comprises the entire gene and entire promoter (hUCP2.BAC deposited with the ATCC; e.g. see pages 16-17). Further, the application teaches the isolation of a lambda EMBL3 phage comprising ~14 kb of human sequences. This clone comprises all 8 exons of the human UCP-2 gene, as well as a minimum of 3 kb of DNA upstream of the putative +1 site (e.g. page 32). The application teaches methods of screening compounds for the ability to modulate (e.g. increase or inhibit) the activity or expression of UCP-2. Such methods can be performed *in vivo* or *in vitro* using cells expressing the human UCP-2 gene (or cells expressing a reporter sequence operatively linked to the UCP-2 regulatory sequences) that are incubated in the presence and absence of test compounds and the level of expression in each case determined (e.g. page 19, lines 2-18). As indicated above, the term "cell differentiation medium" is not clearly and explicitly defined in the instant specification and can thus be read broadly to encompass any media used to culture any of the types of cells taught by Surwit et al.

Given the size of the genomic clones obtained by the inventors of the Surwit et al application (e.g. at least 3 kb upstream of the transcription initiation site) and the fact that the sequences recited in the recent claims are all within ~2.2. kb of the initiation site (e.g. see

amended Figure 4 of the instant specification), it is reasonable to expect that the clones obtained by Surwit et al necessarily comprise the specific sequences recited in rejected claims 1-8. Because the Office does not have the facilities for examining and comparing the applicant's product with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (e.g. that the products of the prior art do not possess the same material structural and functional characteristics of the claimed product). See in re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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PRIMARY EXAMINER